

### **REMARKS**

Claims 1-35 and 37-63 are pending. Claims 36 and 64 are cancelled. Claims 1-29, 33-35 and 37-63 stand withdrawn. Claims 30-32 stand rejected.

With the present Amendment and Reply, Applicants present new claims 65-75. Support for the new claims is found throughout the specification including, but not limited to, paragraphs [0076], [0081]-[0091] and [0101]-[0109] of the published specification.

No new matter is presented. Reconsideration is respectfully requested.

#### **Rejection of Claims 30-32 Under 35 U.S.C. §103(a)**

Claims 30-32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over **van Lengerich** (U.S. Patent No. 6,500,463) in view **Kalbe et al.** (CA 2,413,698). The Examiner contends that one skilled in the art would have been motivated to use the meat flavorings of **Kalbe et al.** in the formulations of **van Lengerich** to arrive at the instantly claimed method.

Applicants respectfully traverse the rejection of claims 30-32 on at least the following grounds: (1) **van Lengerich** and **Kalbe et al.** do not teach or suggest the instantly claimed method; (2) one of ordinary skill in the art would not have been motivated to combine **van Lengerich** and **Kalbe et al.** to arrive at the instantly claimed method; and (3) the combination of **van Lengerich** and **Kalbe et al.** cannot be combined to result in the instantly claimed method.

The instant claims are directed to a method for the production of a highly palatable ductile chewable veterinary composition comprising (A) one or more active ingredients, (B) meat flavoring, (C) partially gelatinized starch, (D) softener, and (E) water in an amount of  $\leq 9\%$ . The highly palatable ductile chewable veterinary composition includes at least one active ingredient that is not decomposed by the interaction with other ingredients, including the meat flavoring and excess water, even at elevated temperatures. The claimed method results a product that is acceptable to animals from the point of view of its physical structure (i.e., a ductile chewable composition). The goal of producing an acceptable product has been achieved by subjecting a formulation to a cold extrusion process with constant cooling so that the temperature at the extruder tip does not exceed 40°C. The consistency of the composition is not changed during this cold extrusion process. Accordingly, the initial composition and consistency is maintained during the extrusion process, and the ductile chewable product is obtained in a very reproducible manner depending on the composition employed.

**Van Lengerich** does not teach or suggest the instantly claimed method for the following reasons. First, **van Lengerich** relates to the encapsulation of active ingredients into a matrix to

obtain discrete shelf-stable particles. Specifically, **van Lengerich** discloses a matrix component comprising at least one plasticizable matrix material and a matrix component which is substantially non-plasticizable for encapsulation of the active ingredient. The **van Lengerich** composition is plasticized by means of a suitable plasticizer (e.g., excess water) the concentration of which is far beyond the percentage recited in claim 30. The plasticizable matrix material is then dried in order to form a glassy coat around the active ingredient (see, for example, **van Lengerich** at column 11, lines 16-31; column 20, lines 53-55). The final product exhibits a non-chewable texture (see column 24, lines 10-14). Accordingly, while the presently claimed compositions are highly palatable ductile and chewable, the compositions disclosed by **van Lengerich** are glassy (i.e., non-ductile) and non-chewable. In addition, the compositions disclosed by **van Lengerich** contain high water (plasticizer) concentrations needed for the plasticizing step, which are outside the scope of the present claims. No plasticizing step (or any other transformation step) is taught or suggested. In fact, such a step would be counter to the purpose of achieving a glassy coat. Instead, **van Lengerich** discloses that mixing the ingredients and extruding the resulting mixture leads to the final product.

Secondly, **van Lengerich** discloses hundreds of active ingredients (columns 15-19) but none of the active ingredients are capable of being incorporated in a composition at the temperatures of the instantly claimed method. In fact, the list disclosed in **van Lengerich**, by contrast, confirms that **van Lengerich** is directed to human medicines and not to veterinary medicinal compositions. This position is further confirmed by the fact that **van Lengerich** does not teach or suggest the utilization of a meat flavor. Flavors are usually a main ingredient of a veterinary medicine making up to 30% of the entire formulation. Accordingly, providing a chewable composition with acceptable physical properties becomes an even more difficult challenge to one skilled in the art, especially if 30% of the formulation is already occupied by the meat flavor.

**Kalbe et al.** do not cure the deficiencies of **van Lengerich**. Specifically, **Kalbe et al.** disclose the manufacture of extruded shaped veterinary articles according to a process which is common for the manufacture of animal food. The process disclosed in **Kalbe et al.** includes extruding a mixture containing the ingredients together with non-gelatinized starch at high temperatures (120°C or above). During the extrusion process the starch is baked and a cookie is produced. Accordingly, the initial composition is again chemically/physically changed, either by plasticizing or by baking at elevated temperatures. In addition, the depsipeptides (i.e., the active ingredients) are obviously temperature-stable and do not suffer from interactions with other components of the composition.

Contrary to the methods disclosed in the **van Lengerich** and **Kalbe et al.**, the initial formulation of the instantly claimed methods is not changed during the presently claimed extrusion method. As a result, the product is obtained in a more reproducible manner. Furthermore, the disclosed **Kalbe et al.** process cannot be used to produce the products produced by the instantly claimed method because the instant active ingredients employed are temperature-sensitive. Thus, **Kalbe et al.** do not cure the deficiencies of **van Lengerich** or provide the requisite motivation to combine with **van Lengerich**. The disclosures of **van Lengerich** and **Kalbe et al.** cannot be combined to result in the instantly claimed method.

Applicants respectfully request withdrawal of the rejection of claims 30-32 and allowance of the pending claims.

**CONCLUSION**

The claims are believed in condition for allowance and Applicants respectfully request such action. The Examiner is invited to contact Applicants' undersigned representative with any questions or comments for expeditious handling.

Respectfully submitted,

Date: 15 April 2010

Amy H. Fix  
Amy H. Fix  
Registration No. 42,616  
Attorney for Applicants

Docket: H-33301A (N079 1450US)

Womble Carlyle Sandridge & Rice, PLLC  
Post Office Box 7037  
Atlanta, Georgia 30357-00378

Direct Telephone: (919) 484.2314  
Direct Facsimile: (919) 484.2071